

REMARKS

Claims 11-14 are pending in the subject application.

Applicant wishes to thank Examiner Aulakh for the courtesy of telephonic interviews held on April 28, 2006 and May 4, 2006.

I. Obviousness Rejections under 35 U.S.C § 103(a)

The Examiner rejected claims 11-14 under 35 U.S.C § 103(a) as allegedly being obvious over U.S. Patent No. 6,476,043 B1 to Toutain et al. ("Toutain") or U.S. Patent No. 6,545,010 B2 to Bissery ("Bissery") for the reasons set forth on page 2, section 2 of the Final Office Action. In particular, the Examiner asserted that "the therapeutic effect of [the] instant composition is solely due to irinotecan and the therapeutic utility of irinotecan is well known in the prior art." The Examiner further asserted that "applicants have not provided any unexpected results of either superior activity or reduced side effects by the instant combination over the prior art known composition comprising irinotecan."

A telephonic interview was held on April 28, 2006, which included Examiner Aulakh and Applicant's attorneys David L. Kershner (Reg. No. 53,112) and Jason G. Tebutt (Reg. No. 55,671). In the interview, Applicant's attorneys noted that the invention was directed to a pharmaceutical composition comprising irinotecan and/or at least one salt thereof in a therapeutically effective total amount and 4-amino-3-propionylphenyl-1,4'-bipiperidine-1'-carboxylate and/or at least one salt thereof in a detectable amount. Applicant's attorneys also noted that the combination of the recited compounds was not taught or suggested in either Toutain or Bissery. Applicant's attorneys explained that the claimed composition contained a detectable amount of 4-amino-3-propionylphenyl-1,4'-bipiperidine-1'-carboxylate, which is useful as an analytical marker. Therefore, Applicant's attorney stated that a showing of "unexpected results of either superior activity or reduced side effects" was not required. Examiner Aulakh said that he would reconsider the rejection in view of our arguments.

In a telephonic interview held on May 4, 2006, Examiner Aulakh agreed to allow pending claims 11-14. Examiner Aulakh indicated that a terminal disclaimer was still required (see below).

II. Rejection of Claims 11-14 Based on the Ground of Nonstatutory Obviousness-type Double Patenting

The Examiner rejected claims 11-14 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6 and 7 of U.S. Patent No. 6,723,729. In

particular, the Examiner stated that “[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because irinotecan or a salt prepared by using 4-amino-3-propionylphenyl-1,4'-bipiperidine-1'-carboxylate or a salt is claimed in the cited patent and furthermore, the therapeutic utility of irinotecan for treating cancer is well known in the art.” Applicant disagrees with the Examiner’s position. However, in order to advance prosecution, Applicant is submitting herewith a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c).

In view of the above, Applicant requests that the nonstatutory obviousness-type double patenting rejection of claims 11-14 be withdrawn.

III. Conclusion

In view of the above remarks, Applicant submits that the present claims are now in condition for allowance. Applicant does not believe any additional fee(s) are due in connection with this Amendment. However, if any additional fee(s) is due, Applicant’s attorney authorizes payment from deposit account number 16-1445 or the credit of any overpayment to the aforementioned deposit account.

If the Examiner wishes to comment or discuss any aspect of this application or response, Applicant’s undersigned attorney invites the Examiner to call him at the telephone number provided below.

Respectfully submitted,

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